

# **EXHIBIT 1**

***Iran Thalassemia Society v. OFAC***

**MEDICAL REPORT OF DR. NOURBAKHS**





(Patients with Thalassaemia Must Bear a High Cost for Treatment. Please Assist Us to Support Them)

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### Medical Report of Dr. Nourbakhsh

#### **In the name of God**

*Human beings are members of a whole  
In creation of one essence and soul  
If one member is afflicted with pain  
Other members uneasy will remain  
If you've no sympathy for human pain  
The name of human you cannot retain*

I was requested to conduct an investigation into the conditions of children suffering from thalassemia major who are affiliated with the Iran Thalassaemia Society. The ages of the children are from 3 to 11 years of age and the children were from locations across Iran. Before describing the outcome of that investigation it is necessary to provide a brief description on the disease of thalassemia major.

Thalassemia major is a hereditary disease or disorder that causes anemia. Severe anemia is usually diagnosed during infancy, and if diagnosed on time, the patient may enjoy a normal life by using blood transfusions to counter the anemia. However, blood transfusions cause an increase in the internal iron load in the patient's body, and as a result the patient should be treated with iron-releasing drugs, or "iron chelators."

For thalassemia patients receiving transfusions, iron chelators should be taken regularly throughout the life of the patient. The failure to use iron chelators regularly will lead to an accumulation of iron in vital human organs, including the heart, brain, internal glands such as thyroid and parathyroid, liver, spleen and gonads. Accumulation and piling of iron in these organs causes a disturbance in the functioning of vital tissues; if the drugs are not taken, the patient will suffer from organ failure and opportunistic infections – the patient is doomed.

Patients who regularly take standard iron chelating drugs at appropriate doses and intervals can enjoy a normal life. They will not experience common symptoms of the disease such as facial deformation and their internal glands and vital organs will be in a normal state; thalassemia journals indicate that the use of high-quality drugs to treat iron toxicity is the most effective factor in creating an optimal life for those disease-suffering patients. The emotional and mental state of patients who regularly receive appropriate

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drug treatment is stable and balanced, compared to patients who do not receive the drugs. Returning to a discussion of the subject children, the children in this investigation were chosen randomly from among child thalassemia sufferers. Two of the children died in the three years preceding the preparation of the results of this investigation. The names and source locations of the children are as follows:

Names, ages, and locations of the children:

- 1- [redacted], 10 years old, from Zabol city. (died)
- 2- [redacted], 10 years old, from Lorestan province. (died)
- 3- [redacted], 6 years old, from Zahedan province. (died)
- 4- [redacted], 10 years old, from Jiroft city.
- 5- [redacted], 5 years old, from Jahrom city.
- 6- [redacted], 4 years old, from Zabol city.
- 7- [redacted], 6 years old, from Zabol city.
- 8- [redacted], 10 years old, from Hormozgan province.
- 9- [redacted], 6 years old, from Zabol city.
- 10- [redacted], 6 years old, from Zabol city.
- 11- [redacted], 9 years old, from Zabol city.
- 12- [redacted], 11 years old, from Zabol city.

Notes:

- All 12 patients with thalassemia major were children under 11 years of age. The diagnosis of thalassemia major was confirmed by laboratory test and standard electrophoresis in an accredited standard reference laboratory.
- None of these patients took the standard high-quality iron chelator drugs (injectable Desferal or JANDENU) regularly.
- These iron chelator drugs taken by these patients were imported from either China or India and had unknown active ingredients, were marketed under unconventional brands, and were not consumed regularly. A number of the children had no access to any iron chelator drugs.
- Heart failure is the most common cause of death in the patients, and the cause of heart failure in these patients is secondary hemochromatosis (iron deposition in the vital cells of the heart and destruction of the heart's pumping function and conduction system, cardiac nerves) in these patients.

A number of the child patients were admitted to the hospital several times and, when iron chelators were not available, secondary hemochromatosis had become more severe and it had caused heart failure and then liver failure for these patients.

A major cause of death of the patients was the non-use of Desferal, an injectable iron chelator, which is produced by an European-American company. The injectable medicine






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is prepared in special solvents for use by a drug injection pump called the "Desferal Injection Pump Device," which the patient uses to inject the drug subcutaneously in the skin of the abdomen or arm. Unfortunately, Desferal injection pumps are manufactured in Europe and America, and because of the cruel sanctions these devices have not recently been imported into Iran. New thalassemia patients cannot obtain this device.

As noted, if standard quality drugs are available and used regularly and if there is no financial impediment to the drugs' acquisition, the patient may live as long as a person not afflicted by the disease. On the other hand, if the thalassemia patient does not have access to standard quality drugs in his/her country and has to resort to a smuggled drug at a high price and unknown quality, he/she will suffer from many medical problems caused by inadequate treatment of thalassemia and presence of side effects. These problems are the main cause of deaths among these patients.

A patient who is forced to use inappropriate or unconventional medicine or who has no access to the correct medicine can live for up to two to three years. In these cases, the medical cause of death is secondary hemochromatosis and heart and liver complications. The monopoly period for a new drug is usually ten years globally, which means that any pharmaceutical company that successfully invents and registering a drug molecule can own the intellectual and material property rights to the drug for ten years. Neither India nor China adhere to this drug monopoly law.

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